

U.S.S.N. 09/453,109
Filed: December 2, 1999
**AMENDMENT AND
RESPONSE TO OFFICE ACTION**

In the Claims

Please substitute the following claims for the pending claims having the same numerals:

AS Sub B1
1. (Once amended) A device for collecting a sample of a biological fluid comprising:
one or more hollow or porous microneedles, each having a base end and a tip,
wherein the microneedle has a length between about 500 μ m and 1 mm and a width between
about 1 μ m and 500 μ m;
a substrate to which the base of the microneedle is attached or integrated, wherein
the microneedle is perpendicular to or extends at an angle from a surface of the substrate; and
at least one collection chamber which is selectably in fluid communication with
the base end of the microneedle.

2. (Once amended) The device of claim 1 further comprising a means for inducing
transport of a biological fluid or component thereof into the collection chamber.

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7. (Once amended) The device of claim 3 wherein the means for inducing transport
comprises a plunger movably secured to the substrate, wherein the plunger can deform the
collection chamber.

8. (Once amended) The device of claim 6 wherein the collection chamber comprises a one-
way valve.

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11. (Once amended) The device of claim 1 further comprising an adhesive material for
securing the device to a biological barrier surface during fluid withdrawal or sensing.

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A8 15. (Once amended) A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip, wherein the microneedle has a length between about 500 μ m and 1 mm and a width between about 1 μ m and 500 μ m;

a substrate to which the base of the microneedle is attached or integrated, wherein the microneedle is perpendicular to or extends at an angle from a surface of the substrate; and at least one sensor which is selectably in communication with the microneedle.

16. (Once amended) The device of claim 15 wherein the sensor comprises:

a chemical or biochemical agent that react with an analyte, and electrochemical or optical transducers which measure the reaction of the agent and the analyte.

A9 20. (Once amended) A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip, wherein the microneedle has a length between about 500 μ m and 1 mm and a width between about 1 μ m and 500 μ m; and

a substrate to which the base of the microneedle is attached or integrated, wherein the microneedle is perpendicular to or extends at an angle from a surface of the substrate; wherein at least one of the microneedles is or comprises a sensor.

21. (Once amended) The device of claim 20 wherein the sensor comprises:

a chemical or biochemical agent that react with an analyte, and electrochemical or optical transducers which measure the reaction of the agent and the analyte.

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27. (Once amended) A method for collecting a sample of a biological fluid or analyte therein, comprising the steps:
- providing the device of claim 2;
 - inserting the microneedles of the device into a biological barrier comprising biological fluid; and
 - triggering the means for inducing to permit the transport of a quantity of the biological fluid or an analyte therein through the microneedles and into the collection chamber.
28. (Once amended) The method of claim 27 wherein the means for inducing is selected from the group consisting of capillary action, diffusion, mechanical pumps, electroosmosis, electrophoresis, convection, and combinations thereof.
29. (Once amended) The method of claim 27 wherein the means for inducing utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

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31. (Once amended) A method sensing an analyte in a biological fluid, comprising the steps:
- providing the device of claim 15;
 - inserting the microneedles into a biological barrier comprising biological fluid which contains an analyte; and
 - contacting the sensor with the biological fluid, thereby sensing the analyte.

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32. (Once amended) The method of claim 31 wherein the device further comprises:
at least one collection chamber which is selectably in fluid connection with the
base end of the microneedle, and
a means for inducing transport of the biological fluid or component thereof into
the collection chamber,
wherein, after the microneedles are inserted, the means for inducing is triggered to
draw the biological fluid or an analyte therein through the microneedles and into the collection
chamber.

33. (Once amended) The method of claim 32 wherein the means for inducing utilizes a
pressure gradient in which the pressure within the microneedles and/or collection chamber is less
than the pressure of the biological fluid adjacent the tip of the microneedle.

Please add the following new claims:

38. (New) The device of claim 1 wherein the microneedle comprises a metal.
39. (New) The device of claim 38 wherein the microneedle consists essentially of a metal.
40. (New) The device of claim 1 wherein the microneedle is hollow.
41. (New) The device of claim 1 wherein the microneedle is perpendicular to a surface of the
substrate.
42. (New) The device of claim 15 wherein the microneedle comprises a metal.
43. (New) The device of claim 42 wherein the microneedle consists essentially of a metal.
44. (New) The device of claim 15 wherein the microneedle is hollow.

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45. (New) The device of claim 15 wherein the microneedle is perpendicular to a surface of the substrate.

46. (New) The device of claim 1 wherein the microneedle has a diameter between about 40 and 120 μm .